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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,512	11/07/2001	Jonathan S. Hott	015280-287120US	2394

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[REDACTED] EXAMINER

NOLAN, PATRICK J

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1644

DATE MAILED: 07/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>10/005,512</b>	Applicant(s) <b>Hott et al.</b>	
	Examiner <b>Patrick J. Nolan</b>	Art Unit <b>1644</b>	
	-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --		
<b>Period for Reply</b> A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. <ul style="list-style-type: none"> <li>- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>			
<b>Status</b> <p>1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Apr 25, 2003</u></p> <p>2a) <input type="checkbox"/> This action is <b>FINAL</b>.      2b) <input checked="" type="checkbox"/> This action is non-final.</p> <p>3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11; 453 O.G. 213.</p>			
<b>Disposition of Claims</b> <p>4) <input checked="" type="checkbox"/> Claim(s) <u>1-15</u> is/are pending in the application.</p> <p>4a) Of the above, claim(s) <u>12-15</u> is/are withdrawn from consideration.</p> <p>5) <input type="checkbox"/> Claim(s) _____ is/are allowed.</p> <p>6) <input checked="" type="checkbox"/> Claim(s) <u>1-11</u> is/are rejected.</p> <p>7) <input type="checkbox"/> Claim(s) _____ is/are objected to.</p> <p>8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.</p>			
<b>Application Papers</b> <p>9) <input type="checkbox"/> The specification is objected to by the Examiner.</p> <p>10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).</p> <p>11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.</p> <p>12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.</p>			
<b>Priority under 35 U.S.C. §§ 119 and 120</b> <p>13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</p> <p>a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of:</p> <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> Certified copies of the priority documents have been received.</li> <li>2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.</li> <li>3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> </ol> <p>*See the attached detailed Office action for a list of the certified copies not received.</p>			
<p>14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).</p> <p>a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.</p> <p>15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</p>			
<b>Attachment(s)</b> <p>1) <input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). <u>5</u></p> <p>4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input type="checkbox"/> Other: _____</p>			

**Part III DETAILED ACTION**

1. Claims 1-15 are pending.

2. Applicant's election with traverse of Group I, claims 1-11 in Paper No. 3 is acknowledged. The traversal is on the ground(s) that a search of the methods would unquestionably require searching the art pertaining to immunotoxins per se and as such would not be an undue burden on the Examiner. This is not found persuasive because the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the product as claimed, the immunotoxin can be used in an in vitro assay or in an in vivo method to cause myasthenia gravis in experimental animals..

The requirement is still deemed proper and is therefore made FINAL.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has no support for the term muscle toxin in base claims 1 and 6. Abrin and ricin are cellular toxins they are not specifically muscle toxins. What allows the toxin to only kill nicotinic acetylcholine receptor bearing muscle cells is the antibody component, not the toxin component.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Tuesday through Friday from 9:00 am to 5:30 pm.

5. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-

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3973. The FAX number for our group, 1644, is (703) 305-7401. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

*Patrick J. Nolan*

Patrick J. Nolan, Ph.D.  
Primary Examiner, Group 1640  
July 13, 2003